The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper ~~240~~ 3

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

YUNG-CHI CHENG,

Junior Party,
(Application 08/463,960)

v.

BERNARD BELLEAU, Deceased,
by PIERRETTE BELLEAU and NGHE NGUYEN-BA,

Senior Party,
(Patent 5,532,246 and Reissue Application 09/585,431)

Patent Interference No. 104,396

Before: McKELVEY, Senior Administrative Patent Judge, and GARDNER-LANE and TIERNEY, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

FINAL JUDGMENT

As discussed in the Memorandum, Opinion and Order, Belleau has convincingly demonstrated that the racemate and the (-)-enantiomer are separate patentable inventions. (Paper No. 233, p. 50). As such, the interference was redeclared with new Counts 4 and 5, which read as follows:

Count 4. A method of treating hepatitis B virus infection and/or inhibiting hepatitis B virus replication in a patient in need thereof comprising: administering to said patient an effective amount of BCH-189 or a pharmaceutically acceptable salt, ester or salt of an ester thereof.

Count 5. A method of treating hepatitis B virus infection and/or inhibiting hepatitis B virus replication in a patient in need thereof comprising: administering to said patient a composition comprising an effective amount of (-)-cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one or a pharmaceutically acceptable salt, ester or salt of an ester thereof, wherein the composition contains no more than about 5 weight percent of the corresponding (+) enantiomer, and wherein the weight percent is based on the total combined weight of the (-) and (+) enantiomers.

(Paper No. 233, p. 51). To aid the Board in redeclaring the interference, the parties were invited to provide proposed claim correspondences for the two new counts. Specifically, the parties were to jointly submit a statement of the claim correspondences upon which there was agreement and to provide comments regarding those claim correspondences for which no agreement could be reached.

The parties currently pending claims are as follows:[1,2]

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[1]As discussed in the Memorandum, Opinion and Order, Cheng's Renewed Proposed Amendment (Paper No. 193) is to be entered into Cheng's involved U.S. Application 08/463,960. Additionally, Cheng's amendment canceling claim 224 and adding new claim 225 is to be entered into Cheng's involved '960 application. The "currently pending" claims reflect the status of the claims upon entry of these amendments.

[2]We note that upon entry of Cheng's Amendment to Cancel Dependent Claim 224, claims 170, 171 and 172 will depend from canceled claim 224. ***Should Cheng seek further prosecution of the '960 application, Cheng shall submit an amendment amending claims 170, 171 and 172 to depend from new claim 225.*** For purposes of this Judgment, it is assumed that claims 170, 171 and 172 depend from new claim 225.

Cheng, Application 08/463,960:	37-39, 41, 43, 45-47, 49, 51, 52, 54-56, 58-60, 62-64, 66, 72; 74-78, 84, 86-90, 96, 98-102, 105, 107, 108, 111, 113, 114, 120, 122-126, 132, 134-138, 144, 146-150 and 152-223 and 225.[3]
Belleau, U.S. Patent 5,532,246:	1-9
Belleau Application 09/585,431:	1-15

As set forth in the parties "Joint Statement on Claim Correspondence" (Paper No. 234), the parties have ***disagreed*** on the following claim correspondences:

Cheng, Application 08/463,960:	170-172 and 224.
Belleau, U.S. Patent 5,532,246:	3 and 4
Belleau Application 09/585,431:	3 and 4

(Paper No. 234, p. 2).

Generally, the parties have disagreed as to the scope of the terminology "comprising (-) enantiomer." Belleau takes the position that the term "(-) enantiomer" means the (-)-enantiomer in its pure form, i.e., having at least 95% purity of the (-)-enantiomer in relation to the (+)-enantiomer. (Paper No. 237, pages 2-3). Furthermore, Belleau argues that the term "comprising" cannot be interpreted as allowing the addition of more than 5% (+)-enantiomer as the term comprising does not allow the addition of elements inconsistent with the recited limitations of the claims. In contrast, it is Cheng's position that the term "comprising" allows for the inclusion of additional elements such as the (+)-enantiomer for a claim "comprising" the (-)-enantiomer. (Paper No. 236, p. 6). To resolve the parties dispute, we first construe the meaning of the term (-)-enantiomer and then the term "comprising."

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[3]Taken from Cheng's Amendment to Cancel Dependent Claim 224 (Paper No. 239, p. 3).

The Meaning of the Term (-)-Enantiomer in this Interference

In interpreting the claims and their terms, we apply the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise may be afforded by written description contained in applicant's specification. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In providing the broadest reasonable meaning for the claim terms we are also mindful that there is a heavy presumption in favor of the ordinary meaning of claim language. *Kraft Foods Inc. v. International Trading Co.*, 203 F.3d 1362, 1366, 53 USPQ2d 1814, 1817 (Fed. Cir. 2000).

Both Cheng and Belleau have presented evidence demonstrating that the term (-)-enantiomer represents a distinct concept from the term racemate and (+)-enantiomer. For example, Belleau's '246 patent states that when the (-) enantiomer is employed, it is preferably:

> [S]ubstantially free of the corresponding (+) enantiomer, that is to say no more than about 5 % w/w of the (+) enantiomer, preferably no more than about 2%, in particular less than about 1 % w/w will be present.

(Belleau '246, col. 2, lines 42-46). Similarly, Cheng's involved application 08/463,960, states that:

> Without wishing to be bound by any particular theory of operability, it is possible that the virus DNA polymerase is able to interact with the unnatural (-)-configuration. It can be expected that the therapeutic index of (-)-3'-thia-2',3' -dideoxycytidine should be better than the (+)- or (±) -form of 3'-thia-2',3' -dideoxycytidine or its analogues.

(BX 2070, pages 1588-1589, emphasis added). As such, on the facts presented, there is convincing evidence that the term (-)-enantiomer, as used by the parties, is distinct from the

terms racemate and (+)-enantiomer.

There is convincing evidence of record that one skilled in the art would understand that the term (-)-enantiomer refers to the (-) enantiomer in its pure form with the understanding that the pure (-) enantiomer nevertheless may contain some amount of contamination of the (+) enantiomer. For example, Dr. Doong, testified that:

> My definition minus would be like hundred percent minus. That – [sic] what the definitions are, the minus would be minus, plus would be plus.

(Deposition Testimony of Dr. Doong, Cheng Record, p. 262, lines 4-7). Similarly, Dr. Cheng testified that his "definition of the (-) enantiomer is more than 95 percent purity of (-)-enantiomer." (Deposition Testimony of Dr. Cheng, Cheng Record, p. 208, lines 13-15). Moreover, as noted in the Decision on Preliminary Motions (Paper No. 189), Belleau has submitted evidence demonstrating that the (-)-enantiomer is likely to have some contamination of the (+)-enantiomer present, e.g., 1 or 2%. (Paper No. 189, p. 24, BX 2075, p. 915; BX 2102, p. 7295).

In light of the facts presented, we hold that the term (-)-enantiomer refers to the (-)-enantiomer in its pure form with only a minor amount of contamination of the (+)-enantiomer. Giving the term "(-)-enantiomer" its broadest reasonable meaning as understood by one of ordinary skill in the art, we further hold that the term "(-)-enantiomer" contains, <u>at most</u>, no more than 5 weight percent contamination of the (+)-enantiomer.

<u>The Meaning of the Phrase "Comprising (-)-Enantiomer"</u>

The term "comprising" allows for the addition of other unrecited elements to the claimed

invention so long as the named elements, which are essential, are included. *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). It is understood, however, that the open-ended transition "comprising" does not free a claim from its own limitations. Specifically, the use of the transition term "comprising" cannot restore subject matter that is otherwise excluded from the claim. *Kustom Signals* Inc. v. *Applied Concepts, Inc.*, 264 F.3d 1326, 1332, 60 USPQ2d 1135, 1139 (Fed. Cir. 2001); *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1379-80, 49 USPQ2d 1065, 1070 (Fed. Cir. 1998). As we have construed the term "(-)-enantiomer" to include, at most, no more than 5 weight percent of the (+)-enantiomer, the term comprising cannot open a claim to the (-)-enantiomer to the inclusion of more than 5 weight percent of the (+)-enantiomer.[4]

We note that a claim directed towards an "admixture" of the (-)-enantiomer and the (+)-enantiomer allows for the presence of major amounts of either the (-) or the (+)-enantiomer. Specifically, such a claim merely requires that the two components, i.e., the (-) and (+)-enantiomer, both be present. For example, a claim to an "admixture" of the (-)-enantiomer and the (+)-enantiomer could have 20% of the (-)-enantiomer (which is defined in this interference to contain at most 5% of the corresponding (+)-enantiomer) and 80% of the (+)-enantiomer. The

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[4]We note that Belleau claim 4 is directed to a method employing a compound of formula (I), wherein the compound of formula (I) "comprises" the (-)-enantiomer. Belleau claim 5 depends from Belleau claim 4 and states that the compound of formula (I) "is substantially free of the corresponding (+)-enantiomer." It is unclear on this record whether the doctrine of claim differentiation would require Belleau claim 4 to ***not*** be substantially free of the corresponding (+)-enantiomer. As the parties did not address this issue and as it is not clear that the doctrine of claim differentiation applies, we maintain our holding that the terminology "comprising (-)-enantiomer" allows for no more than 5 weight percent of the corresponding (+)-enantiomer.

reason for the difference in claim scope between the "comprising (-)-enantiomer" and the "admixture of the (-) and (+) enantiomer" is due to the specific notice provided by the applicant that the admixture claim places no limit on the amount of specifically recited (+)-enantiomer, whereas the "comprising (-)-enantiomer" claim, read in light of the evidence presented, indicates that the parties have notified the public that the term (-)-enantiomer, by and of itself, cannot contain more than 5 weight percent of the corresponding (+)-enantiomer.

The Counts and the Parties' Claim Correspondence

The counts in this interference are as follows:

Count 4. A method of treating hepatitis B virus infection and/or inhibiting hepatitis B virus replication in a patient in need thereof comprising: administering to said patient an effective amount of BCH-189 or a pharmaceutically acceptable salt, ester or salt of an ester thereof.

Count 5. A method of treating hepatitis B virus infection and/or inhibiting hepatitis B virus replication in a patient in need thereof comprising: administering to said patient a composition comprising an effective amount of (-)-cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one or a pharmaceutically acceptable salt, ester or salt of an ester thereof, wherein the composition contains no more than about 5 weight percent of the corresponding (+) enantiomer, and wherein the weight percent is based on the total combined weight of the (-) and (+) enantiomers.

(Paper No. 233, p. 51).

The parties' claims corresponding to Count 4 are:

Cheng, Application 08/463,960:	41, 45, 49, 54, 58, 62, 66, 74, 86, 98, 107, 113, 122, 134, 146, 156-159, 170-173, 175-176, 178-818, 187, 193, 199, 202, 205, 211, 217, 223, 225
Belleau, U.S. Patent 5,532,246:	1-3 and 6-9
Belleau Application 09/585,431:	1-3, 6-9, 10, 12, 14

The parties' claims that do not correspond to Count 4 are:

Cheng, Application 08/463,960:	37-39, 43, 46-47, 51-52, 55-56, 59-60, 63-64, 72, 75-78, 84, 87-90, 96, 99-102, 105, 108, 111, 114, 120, 123-126, 132, 135-138, 144, 147-150, and 152-155, 160-169, 174, 177, 182-186, 188-192, 194-198, 200-201, 203-204, 206-210, 212-216 and 218-222.
Belleau, U.S. Patent 5,532,246:	4-5
Belleau Application 09/585,431:	4-5, 11, 13 and 15

The parties claims corresponding to Count 5 are:

Cheng, Application 08/463,960:	37-39, 43, 46-47, 51-52, 55-56, 59-60, 63-64, 72, 75-78, 84, 87-90, 96, 99-102, 105, 108, 111, 114, 120, 123-126, 132, 135-138, 144, 147-150, and 152-155, 158-169, 174, 177, 182-186, 188-192, 194-198, 200-201, 203-204, 206-210, 212-216 and 218-222.
Belleau, U.S. Patent 5,532,246:	1-2 and 4-9
Belleau Application 09/585,431:	1-2 and 4-15

The parties claims that do not correspond to Count 5 are:

Cheng, Application 08/463,960:	41, 45, 49, 54, 58, 62, 66, 74, 86, 98, 107, 113, 122, 134, 146, 156-159, 170-173, 175-176, 178-818, 187, 193, 199, 202, 205, 211, 217, 223, 225
Belleau, U.S. Patent 5,532,246:	3
Belleau Application 09/585,431:	3

It is:

ORDERED that Cheng's Amendment to Cancel Dependent Claim 224 and Rewrite it as Independent Claim 225 (Paper No. 239) will be entered into Cheng's involved U.S. Application No. 08/463,960.

FURTHER ORDERED that Junior Party Cheng is not entitled to a patent containing claims 37-39, 41, 43, 45-47, 49, 51, 52, 54-56, 58-60, 62-64, 66, 72, 74-78, 84, 86-90, 96, 98-102, 105, 107, 108, 111, 113, 114, 120, 122-126, 132, 134-138, 144, 146-150 and 152-223 and 225 of Cheng's involved U.S. Application No. 08/463,960.

FURTHER ORDERED that a copy of this final decision shall be placed and given a paper number in the file of Belleau et al., U.S. Patent No. 5,532,246, Belleau et al., U.S. Application 09/585,431 and Cheng, U.S. Application No. 08/463,960.

FURTHER ORDERED that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c) and 37 CFR § 1.661.

FRED E. McKELVEY
Senior Administrative Patent Judge

SALLY GARDNER-LANE
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